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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,516	10/01/2003	W. Gary Erwin	036806.00438	8336

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EXAMINER

NGUYEN, TRAN N

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/676,516	Applicant(s) ERWIN, W. GARY	
	Examiner Tran Nguyen	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 12/29/2003.

Pending claim(s): 1-5.

Priority

Acknowledgment is made of Applicant's claim for priority to application 60414995 filed 10/01/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/29/2003 is entered and considered by Examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 1-15 is/are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As per claim 1, this claim recites a "method".

First, each method step does not require the particulars of a “machine”. Therefore, any structure capable of performing the recited functionality may be reasonably enveloped by the claim.

Second, although the claim recites “providing... recommendations”, this limitation amounts to mere data transformation at best, and do not provide a physical transformation.

Therefore, the claim fails the "machine or transformation" test, and is directed towards nonstatutory subject matter.

All claims dependent thereon, namely claims 2-5, fail to remedy these deficiencies, and are therefore rejected for at least the same rationale above, and incorporated herein.

As per claims 6-15, these claims are rejected for at least the same rationale as applied to claims 1-5 above, and incorporated herein.

Additional clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1, 3-4, 7-11, 13 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (5832448).

As per claim 1, Brown teaches a method (Abstract) capable of monitoring (reads on “managing”) a group of patients (reads on “the healthcare of members of a population”) (Abstract), comprising:

(a) providing supervisory instructions to the patients (reads on “identifying key characteristics”, wherein the patients are instructed to record physiological measurements, and is considered to be "key characteristics") (Figure 6 label 220, 200);

(b) receiving the patient's measurements (reads on "demographic and medical information", wherein the patient measurements contain a patient identifier) (Figure 6 label 202);

(c) storing the received measurements in a database (reads on "organizing, structuring, and storing") (Figure 6 label 204);

(d) calculating a control value for the patient (reads on "a set of logical rules") based on the received measurements (Figure 6 label 206);

(e) retrieving the measurements (Figure 6 label 208);

(f) using the retrieved measurements to determine the patient's compliance based on the calculated control value (Figure 6 label 208);

(g) revising the supervisory instructions based on the analysis (Figure 6 label 220).

As per claim 3, Brown teaches determining the patient's compliance with the prescribed treatment plan (column 8 line 24-28).

As per claim 4, Brown teaches furthering monitoring patients (reads on "follow-up checks") for all patients (reads on "if the medical treatment outcome... is acceptable") (Figure 6).

As per claim 7, this claim is rejected for substantially the same rationale as applied to claim 1 above, and incorporated herein.

In particular, Examiner considers analyzing the patient's measurements in view of the control value to be analyzing a portion of "a stratified set of risks".

As per claim 8, Brown teaches modifying the treatment plan and control value therefor accordingly (Figure 6 label 220, 206).

As per claim 9, Brown teaches grouping patients by a grouping, e.g. diabetes (Figure 3).

As per claims 10-11, Brown teaches using the system to predict which patients are likely to neglect their health care (Figure 6). Brown further teaches contacting rogue patients (Figure 8).

As per the set of claim(s): 13, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 3, respectively, and incorporated herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 2, 12 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Applicant Admitted Prior Art (AAPA).

As per claim 2, Brown does not teach "de-identifying".

Page 6 of the specification discloses:

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[0019] Data-gathering step 115 may optionally include de-identification of the data in any conventional manner to achieve compliance with any applicable patient privacy regulations, such as those found in the U.S. Health Insurance Portability and Accountability Act ("HIPAA"). In particular, 45 C.F.R. Parts 160 and 164 of the Act relate to standards for the privacy of individually-identifiable health information (the "Privacy Rule"), promulgated by the Department of Health and Human Services (HHS). In part the Privacy Rule can restrict the acquisition and use of certain types of patient data, particularly individually-identifiable health information.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of 45 CFR 160, 164 within the embodiment of Brown with the motivation of legal compliance.

As per the set of claim(s): 12, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 2, respectively, and incorporated herein.

Claim(s) 5-6, 15 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown.

As per claim 5, Brown teaches monitoring the patient's measurements based on the prescribed treatment plan (Figure 6).

Brown further teaches revising the supervisory instructions as needed (Figure 6).

Brown further teaches communicating with unmotivated patients who have deviated from the treatment plan (column 8 line 55-58).

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Brown does not specifically teach that only noncompliant patients receive revised instructions.

Brown does teach communicating with rogue patients that have abandoned their treatment regimens (Figure 8).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to change only the treatment plans of noncompliant patients within the embodiment of Brown with the motivation of focusing the physician's attention on noncompliant patients, wherein compliant patients are afforded less oversight and supervision.

As per claim 6, this claim is rejected for substantially the same rationale as applied to claims 1, 3-5 above, and incorporated herein.

As per the set of claim(s): 15, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 5, respectively, and incorporated herein.

Claim(s) 14 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Official Notice.

As per claim 14, Brown teaches revising treatment plans as needed (Figure 6).

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Brown does not teach “providing new recommendations” for acceptable outcomes.

Official Notice is taken that when a patient has successfully overcome a disease, it would be prudent to adjust the patient's treatment regimen. This fact is old and well established in the art of health care.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of the Official Notice within the embodiment of Brown with the motivation of changing the patient's treatment regimen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./

Examiner, Art Unit 3626

12/24/2008

/Robert Morgan/

Primary Examiner, Art Unit 3626